DOCKET NO.: ISRT-0327 (RTS-0327)

Application No.: 10/000,213

Office Action Dated: December 16, 2003

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

REMARKS/ARGUMENTS

I. Status of the Claims

Applicants thank the Examiner for her time in a telephone interview to discuss the response to the pending office action.

Claims 1, 2, 4-9, and 11- 29 are pending, with claims 19 and 20 being withdrawn from examination. Claims 19 and 20 have been cancelled without prejudice to pursuing the claims in a continuing application; claims 16-18 and 21-29 were previously cancelled. Claims 1 and 11-15 have been amended. Claim 30 is new. After entry of this amendment, Claims 1, 2, 4-9, 11-15, and 30 will be pending. Support for amendment to the claims and for new claim 30 can be found throughout the specification and, for example, on page 21, 1. 29 to page 22, 1. 33, pages 82 to 84, and in Table 1, pages 83-84. Claim amendments are for purposes of improved clarity or consistency of claim language unless otherwise noted. No claim amendment should be construed as an acquiescence in any ground of rejection. No new matter has been added by this amendment.

Claims 15-18 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 1, 2, 4-9, and 11-15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hmama et al. (Journal of Experimental Medicine, 190: 1583-1594, 1999) in view of Baracchini et al. (U.S. Patent 5,801,154) and Fritz et al. (Journal of Colloid and Interface Science, 195: 272-288, 1997). Claims 21-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hmama et al. (Journal of Experimental Medicine, 190: 1583-1594, 1999) in view of Cowsert (U.S. Patent 6,566,133).

II. Information Disclosure Statement

The Information Disclosure Statement, filed September 12, 2003 has been acknowledged by the examiner.

III. Patentability under 35 U.S.C. § 112, first paragraph

Claims 15-18 have been rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. Applicants have canceled claims 16-18 without prejudice to pursuing the claims in a continuing application. Claim 15 has been amended to recite that the method of

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inhibiting the expression of vitamin D nuclear receptor in cells or tissues comprising contacting said cells or tissues *in vitro*. Claim 15, as amended, is enabled in the specification, for example, on pages 82 to 84 of the specification. Applicants respectfully request that the rejection of claim 15 under 35 U.S.C. § 112 first paragraph be withdrawn.

IV. Patentability under 35 U.S.C. § 103(a)

Claims 1, 2, 4-9, and 11-15 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hmama et al. (Journal of Experimental Medicine, 190: 1583-1594, 1999) in view of Baracchini et al. (U.S. Patent 5,801,154) and Fritz et al. (Journal of Colloid and Interface Science, 195: 272-288, 1997). Applicants traverse the rejection.

Applicants' claims, as amended, are to an oligonucleotide which specifically hybridizes within nucleotides 1710 to 1757 of a nucleic acid molecule encoding human vitamin D nuclear receptor (SEQ ID NO:3) and inhibits the expression of human vitamin D nuclear receptor. The Examiner states that the Hmama et al. reference discloses a 21-base pair phosphorothioate antisense oligonucleotide targeting the start codon of the human vitamin D nuclear receptor. The Baracchini et al. reference allegedly discloses modified or substituted oligonucleotides. The Fritz et al. reference allegedly discloses a composition comprising an antisense oligonucleotide and a pharmaceutically acceptable carrier or diluent comprising a colloidal dispersion system. The Hmama et al. reference in view of the Baracchini et al. and Fritz et al. references do not teach or disclose an oligonucleotide which specifically hybridizes within nucleotides 1710 to 1757 of a nucleic acid molecule encoding human vitamin D nuclear receptor (SEQ ID NO:3) and inhibits the expression of human vitamin D nuclear receptor. The cited references further do not teach the claimed chimeric oligonucleotide. The claimed hybridization region is not taught by the Hmama et al. reference which targets an antisense oligonucleotide to the start codon. Furthermore, modified or substituted oligonucleotides and pharmaceutical compositions comprising antisense oligonucleotides which specifically hybribize within nucleotides 1710 to 1757 of a nucleic acid molecule encoding human vitamin D nuclear receptor (SEQ ID NO:3) are patentable over the Hmama et al. reference in view of the Baracchini et al. and the Fritz et al.

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references. Therefore, claims 1, 2, 4-9, and 11-15 are patentable over the Hmama *et al.* reference in view of the Baracchini *et al.* and the Fritz *et al.* references.

The rejection of claims 1, 2, 4-9, and 11-15 under 35 U.S.C. § 103(a) has been overcome. Therefore, Applicants respectfully request that the rejection be withdrawn.

Claims 21-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hmama et al. (Journal of Experimental Medicine, 190: 1583-1594, 1999) in view of Cowsert (U.S. Patent 6,566,133).

Applicants have canceled claims 21-29 without prejudice to pursuing the claims in a continuing application. Therefore, the rejection of claims 21-29 under 35 U.S.C. § 103(a) is moot.

Since the claims patentably define over the prior art, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

V. Conclusion

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-332-1380.

Date: May 14, 2004

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